



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/454,711	12/06/1999	JOHANNES B. M. M. VAN BREE	16994-012710	4156

30095 7590 10/30/2002

GENZYME CORPORATION C/O TOWNSEND AND TOWNSEND  
AND CREW  
TOWNSEND AND TOWNSEND & CREW, LLP  
TWO EMBARCADERO CENTER, 8TH FLOOR  
SAN FRANCISCO, CA 94111-3834

EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 10/30/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n No.

09/454,711

Applicant(s)

VAN BREE ET AL.

Examiner

Francisco C Prats

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 27-38 is/are pending in the application.
- 4a) Of the above claim(s) 2-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

Art Unit: 1651

#### **DETAILED ACTION**

The request filed on June 17, 2002, for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/454,711 is acceptable and a CPA has been established. An action on the CPA follows.

#### ***Status of Amendments***

On June 25, 2001 (certificate of mailing May 21, 2001), *after* the April 10, 2001, mailing date of the first action on the merits, applicant filed a preliminary amendment canceling claims 1-26 and amending claim non-elected claim 28. Thus, the amended version of claim 1 appearing in the amendment filed October 15, 2001, is not actually a pending claim.

Claims 27-38 are pending.

#### ***Election/Restrictions***

Claims 27-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7, filed March 5, 2001.

Art Unit: 1651

Claims 35-38 are examined on the merits.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 35-38 depend from canceled claim 1. It is therefore unclear what subject matter is encompassed by the claims.

***Claim Rejections - 35 USC § 103***

Claims 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kikuchi et al (J. Clin. Invest. 101(4):827-833 (1998)), de Barsy et al (Birth Defects, Original Article Series, Vol. IX, No.2, pages 184-190 (1973)), and Reuser et al (U.S. Pat. 6,118,045) in view of Bijvoet et al (Biochim. Biophys. Acta 1308:93-96 (1996)) and Van Hove et al (Biochem. Mol. Biol Int'l. 43(3):613-623 (1997)).

The claims recite the treatment of infantile

Art Unit: 1651

Pompe's disease wherein at least 10 mg/kg body weight per week of human acid  $\alpha$ -glucosidase are administered to a patient which survives at least to one year of age. As discussed in the previous office action, each of Kikuchi, de Barsy and Reuser suggest the treatment of Pompe's disease by administering human acid  $\alpha$ -glucosidase to patients in need thereof. Kikuchi, deBarsy and Reuser differ from the claims in that the dosage amounts disclosed therein are smaller than those recited in various embodiments recited in applicant's claims, and that the dosages are not gradually increased as recited in some other embodiments in the claims.

However, de Barsy notes that the lack of significant clinical effects was likely due to the small amount of enzyme administered owing to lack of availability, and that the efforts disclosed therein must be considered preliminary. See p. 189, col. 1. Thus, de Barsy clearly suggests that increased dosage would be desirable in treating the disease. Moreover, each of Reuser (claims 18-20), Bijvoet (abstract at page 94, disclosing *in vitro* internalization of enzyme) and Van Hove (sentence spanning pages 613 and 614, disclosing endocytosis of 110 kD form of the enzyme and delivery to liver and heart upon injection) clearly suggest that relatively large amounts of the enzyme are obtained by the methods disclosed therein, and that

Art Unit: 1651

the enzymes prepared therein are suitably targeted to the desired tissues, including muscle.

Thus, the artisan of ordinary skill, recognizing from de Barsey that high dosages would have been reasonably expected to improve the results disclosed therein, would have been motivated to have increased the enzyme dosage to the amounts recited in applicant's claims, suitable quantities of the enzymes being made available by the techniques disclosed in the Reuser, Bijvoet and Van Hove disclosures.

Moreover, the determination of a suitable dosage regimen, including the gradually increasing dosage regimen recited in the claims, clearly would have been a matter of routine optimization on the part of the artisan of ordinary skill, the determination of suitable treatment regimens being routinely determined in the pharmaceutical arts. Thus, absent some demonstration of an unexpected result, the claims must be considered obvious. In this regard note that the clinical trials described in the specification at pages 37-39 do not appear to present any significant data in that no clear results are presented. Therefore, it is respectfully submitted that no unexpected result has been demonstrated on the record.

No claims are allowed.

Art Unit: 1651

This is a CPA of applicant's earlier Application No. 09/454,711. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco

Art Unit: 1651

C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Francisco C Prats  
Primary Examiner  
Art Unit 1651

FCP  
October 28, 2002